JONES DAY | **Pharmaceutical & Medical Device Regulatory Update**
Vol. III | Issue 1 | March 2016 JONES DAY

Top News

Senate Confirms Califf as New FDA Commissioner
After weeks of opposition, on February 24, 2016, the Senate confirmed Dr. Robert Califf, President Obama's nominee for FDA Commissioner. Although his nomination was not expected to be controversial, several lawmakers had blocked his nomination due to what they claimed was FDA's poor record regarding controlling abuse of prescription painkillers, particularly opioids. Califf, a prominent cardiologist and medical researcher at Duke University, has been a consultant to drug companies and has run a research institute at Duke primarily funded by the pharmaceutical industry, raising concerns among some lawmakers that he was too close to the industry he will be tasked with regulating. In response to the pressure to curb painkiller abuse, Califf along with other FDA leaders launched a plan in early February 2016 calling for a "sweeping review of agency opioids policies."

Amarin and FDA Agree to Landmark Settlement on Truthful, Non-Misleading Off-Label Promotion
On March 8, 2016, Amarin Pharma, Inc. reached a noteworthy settlement in its lawsuit against FDA to protect its First Amendment right to promote Vascepa (icosapent ethyl) capsules for off-label uses with truthful and non-misleading information. The settlement follows an August 2015 grant of preliminary injunction coming from the Southern District of New York's Judge Engelmayer, blocking FDA from pursuing a misbranding suit against Amarin for the company's truthful and non-

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UPCOMING EVENTS

Colleen Heisey will be moderating a panel, "FDLI Hot Topics in Medical Device Law: Unique Device Identifiers," on March 31, 2016, in Washington, D.C.

Save the Date: Plan to join Jones Day for our program on "Compliance in the Precision Medical Era: Legal Considerations for the Contemporary Life Sciences Industry," from

misleading off-label promotion. While the recent settlement brings the litigation to a close, it signals that changes may be afoot with respect to FDA's stance on off-label promotion and, potentially, a more active role for the courts in determining when off-label promotion is permitted.

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11 a.m.–2 p.m. on May 4, 2016, in Washington, D.C. *Details to follow*.

RELATED PRACTICES

- FDA Regulatory & Compliance Counseling
- Health Care
- Life Sciences

FDA to Conduct Two Studies on DTC Drug Advertising

This month, FDA published notices soliciting comments on two planned FDA studies on direct-to-customer ("DTC") prescription drug advertising. The planned studies will investigate how animation and superimposed text in DTC advertising affect consumers' understanding of and attitudes toward advertised drugs. These studies come amid ongoing scrutiny of DTC advertising for prescription drugs and recent cases challenging the traditional bounds of pharmaceutical marketing activities. In the past two months, both the House and Senate introduced bills that would impact DTC advertising, although industry responses have pointed to the First Amendment, which was recently cited with success in the cases *Amarin Pharma, Inc. v. FDA* and *Pacira Pharmaceuticals, Inc. v. FDA*.

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FDA Releases Draft "Deemed to be a License" Guidance, Addresses Exclusivity

On March 14, 2016, FDA notified the public of the availability of a draft guidance for industry regarding its "Implementation of the 'Deemed to be a License' Provision of the Biologics Price Competition and Innovation Act of 2009." The draft guidance describes the Agency's approach to implementing the "deemed to be a license" provision under which a biological product approved under the federal Food, Drug, and Cosmetic Act (the "FDCA") on or before March 23, 2020, will be deemed to be a license under the Public Health Service Act (the "PHSA") on March 23, 2020. The draft guidance explains FDA's current thinking on the "deemed to be a license" language and makes recommendations to sponsors that may be subject to the transition to facilitate alignment of their product development plans with FDA's interpretation of the provision.

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Other News

Senate Committee Approves Seven Bills Toward Effort to Create Companion to House's 21st Century Cures Bill

DOJ Announces Largest Amount Paid by Medical Device Company for AKS Violations

FDA Publishes Prioritized Lists of Guidance Documents for Development and Retrospective Review in FY 2016

FDA Announces New Grant Program to Fund $2M in FY 2017 for Natural History Studies in Rare Diseases

FDA Requires Black Box Warning and Other Measures for Implantable Contraception Device, Allows it to Remain in Market Despite Criticism

GAO Issues Report on FDA's Expedited Programs and Concludes Improvements Needed in Postmarket Safety Data

Director Woodcock Testifies on FDA's Implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA)

Senate HELP Committee Issues Minority Staff Report from Investigation into

Duodenoscope-Related Infections and Calls for, Among Other Things, More Robust Device Surveillance System

Regulatory Updates

FDA Announces Draft EA and FONSI in Support of GE Mosquito
In the March 14, 2016, *Federal Register*, FDA announced the availability for public comment of Oxitec Ltd's submission of a draft environmental assessment ("EA") and a preliminary finding of no significant impact ("FONSI") in support of a field trial of a genetically engineered ("GE") mosquito. The GE mosquito has recombinant DNA that makes the males lethal such that the offspring of the male GE mosquitoes would not survive into adulthood, resulting in a decrease in the population. FDA is considering the draft EA and tentatively agrees with its conclusion that the trial will result in no significant impacts on the environment. Unless something changes FDA's tentative determination, FDA will prepare and release its own revised, final EA and final FONSI. If FDA does not agree with the preliminary conclusion that the trial will result in no significant impacts on the environment, it will prepare an environmental impact statement ("EIS"). FDA will consider comments on this issue. ***Comments are due April 13, 2016***.

FDA Announces Training Program for Staff to Better Understand Device Development Life Cycle
In the March 10, 2016, *Federal Register*, FDA's Center for Devices and Radiological Health ("CDRH") announced the 2016 Experiential Learning Program ("ELP"). The ELP is intended to provide CDRH staff with an opportunity to better understand the policies, laboratory practices, and challenges faced in broader disciplines affecting the device development life cycle. Through the notice, FDA is inviting medical device industry, academia, and health care facilities to request to participate in this formal training program for FDA's medical device staff. ***Requests for participation are due April 11, 2016***.

FDA Announces Public Conference on Administration Statistics Relating to Clinical Trials
In the March 9, 2016, *Federal Register*, FDA, in co-sponsorship with the Drug Information Association, announced a public conference titled "Tenth Annual DIA/Food and Drug Administration Statistics Forum—2016." The public conference is intended to be an open forum for the timely discussion of topics of mutual theoretical and practice interest to statisticians and clinical trialists who develop and review new drugs and biologics. The conference will primarily focus on establishing an ongoing dialogue between industry and regulatory agencies, emphasizing the regulatory and statistical challenges associated with innovative approaches to the design and analysis of clinical trials and measuring progress in designing and implementing innovative solutions. ***The conference takes place from April 25 to April 27, 2016 in Bethesda, Maryland***.

FDA Announces Public Hearing on Regulatory Science Initiatives for Generic Drugs
In the March 9, 2016, *Federal Register*, FDA announced a public hearing that will provide an overview of the current status of regulatory science initiatives for generic drugs and an opportunity for public input on research priorities in this area. FDA is seeking this input from a variety of stakeholders as it fulfills its commitment under the GDUFA to develop an annual list of regulatory science initiatives specific to generic drugs. FDA will take the information obtained from the hearing into account in developing the fiscal year 2017 Regulatory Science Plan. ***The hearing will take place on May 20, 2016, in Silver Spring, Maryland***.

FDA Announces Removal of Obsolete and Redundant Rule Requiring Sponsors to Submit Data of Certain Drug Use in Animal Feed
In the March 7, 2016, *Federal Register*, FDA announced the removal of regulations requiring sponsors to submit data regarding the subtherapeutic use of certain antibiotic, nitrofuran, and sulfonamide drugs administered in animal feed after determining the

regulations obsolete. FDA now has other strategies for assessing the safety of antimicrobial new animal drugs with regard to their microbiological effects on bacterial of human health concern, and the only animal drug use that remains in these regulations occurs elsewhere in the new animal drug regulations. ***The rule is effective April 6, 2016***.

FDA Establishes Docket to Receive Information and Comments on Third-Party Entities that Refurbish, Recondition, Rebuild, Remarket, Remanufacture, Service, or Repair Medical Devices
In the March 4, 2016, *Federal Register*, FDA announced the establishment of a docket to receive information and comments on the medical device industry and health care community that refurbish, recondition, rebuild, remarket, remanufacture, service, and repair medical devices ("third-party entity or entities"). The action is in response to various stakeholders' concerns over quality, safety, and continued effectiveness of medical devices subject to one or more of these activities performed by both original equipment manufacturers and third parties. FDA seeks comments from a wide range of stakeholders, including those who are engaged in one or more of the activities noted previously or who utilize refurbished, reconditioned, rebuilt, remarketed, remanufactured, or third-party serviced and repaired medical devices. ***Comments are due May 3, 2016***.

FDA Issued the Following Draft and Final Guidance Documents:

Draft Guidance for Industry: Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion, March 15, 2016, *Federal Register*. ***Comments are due June 13, 2016***.

Draft Guidance for Industry: Implementation of the "Deemed to be a License" Provision of the Biologics Price Competition and Innovation Act of 2009, March 14, 2016, *Federal Register*. ***Comments are due May 13, 2016***.

Guidance for Industry: Investigating and Reporting Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR Part 1271, March 9, 2016, *Federal Register*.

Draft Guidance for Industry: Evaluating Respiratory Symptoms in Chronic Obstructive Pulmonary Disease, a Patient-Reported Outcome, for the Measurement of Severity of Respiratory Symptoms in Stable Chronic Obstructive Pulmonary Disease: Qualification for Exploratory Use, March 9, 2016, *Federal Register*. ***Comments are due June 7, 2016***.

Draft Guidance for Industry: Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Initial Pediatric Study Plans, March 9, 2016, *Federal Register*. ***Comments are due May 9, 2016***.

Guidance for Industry: Medical Devices and Clinical Trial Design for the Treatment or Improvement in the Appearance of Fungally Infected Nails, March 7, 2016, *Federal Register*.

Guidance for Industry: Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products, March 7, 2016, *Federal Register*.

Guidance for Industry: Environmental Assessment: Questions and Answers Regarding Drugs With Estrogenic, Androgenic, or Thyroid Activity, March 7, 2016, *Federal Register*.

Draft Guidance for Industry: Clinical Considerations for Investigational Device Exemptions for Neurological Devices Targeting Disease Progression and Clinical Outcomes, March 7, 2016, *Federal Register*. ***Comments are due June 6, 2016***.

Draft Guidance for Industry: Labeling for Permanent Hysteroscopically Placed Tubal Implants Intended for Sterilization, March 4, 2016, *Federal Register*. ***Comments are due May 3, 2016***.

Draft Guidance for Industry: Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat Clostridium difficile *Infection Not Responsive to Standard Therapies*, March 1, 2016, *Federal Register*. ***Comments are due May 31, 2016***.

EU Regulatory Notices

EMA Publishes Guidance on Publication of Clinical Data
On March 3, 2016, the European Medicines Agency ("EMA") published detailed guidance for pharmaceutical companies on the requirements to comply with its policy on the publication of clinical data. EMA's policy entered into force on January 1, 2016, and applies to clinical reports contained in all marketing-authorization applications submitted on or after this date. The first reports are expected to be publicly available in September 2016. The guidance consists of four chapters. The first is an introduction with information on the scope and definitions used throughout the text. The second chapter details procedural aspects on the submission of clinical reports. The third chapter gives guidance to companies on how to anonymize clinical reports for the purpose of publication. Finally, the fourth chapter focuses on the identification and redaction of commercially confidential information in clinical reports submitted to EMA for the purpose of publication. EMA will now start reaching out to companies affected by the first wave of publication, i.e., those for which the decision-making process has been finalized since the policy entered into force. In addition, EMA will organize a webinar in the second quarter of 2016 to allow companies to ask any outstanding practical questions.

EMA Launches Priority Medicines Scheme
On March 7, 2016, EMA launched its new Priority Medicines Scheme ("PRIME") for medicines that target an unmet medical need. The scheme focuses on medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients with no treatment options. These medicines are considered priority medicines within the EU. To be accepted for PRIME, a medicine has to show its potential to benefit patients with unmet medical needs based on early clinical data.

European Court of Justice Upholds Orphan Market Exclusivity Judgment
On March 3, 2016, the Court of Justice of the EU ("CJEU") dismissed Teva's appeal against the General Court of the EU's judgment in Case T-140/12 and upheld the General Court's findings that an orphan medicinal product that has the same therapeutic indication as a previously authorized orphan but that has been independently authorized enjoys 10 years of independent market exclusivity. The case was brought by Teva against EMA's decision to reject the marketing authorization application for the generic version of the previously authorized orphan (imatinib) on the basis that the later and independently authorized orphan (nilotinib) continued to have market exclusivity for the therapeutic indication in question.

EMA Reviews Cancer Medicine Zydelig Following a Series of Serious Adverse Events in Ongoing Clinical Trials
On March 11, 2016, EMA announced that it has, at the request of the European Commission, started a review of the cancer medicine Zydelig (idelalisib), which is authorized in the EU to treat two types of rare blood cancers called chronic lymphocytic leukemia and follicular lymphoma (one of a group of cancers called non-Hodgkin lymphoma). The review was triggered by an increased rate of serious adverse events including deaths, mostly due to infections, that was seen in three clinical trials investigating the medicine in combination with other cancer medicines. Investigators of all clinical trials involving Zydelig are currently being informed of the actions to be taken in

relation to the conduct of ongoing studies. EMA will review the data from these studies to assess whether the findings have any consequences for the authorized uses of Zydelig. EMA is also considering whether any other immediate measures are necessary while the review is ongoing. The review is being carried out by the Pharmacovigilance Risk Assessment Committee ("PRAC"), the committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. The PRAC recommendations will then be forwarded to the Committee for Medicinal Products for Human Use (CHMP"), responsible for questions concerning medicines for human use, which will adopt a final opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States

EMA Consults on Risk Management Systems Pharmacovigilance Module
On February 29, 2016, EMA issued a revision of module V of the good pharmacovigilance practices ("GVP") on risk management systems for public consultation. GVP module V, released in 2012, advises developers of medicines, marketing authorization holders, and regulators on the design of effective risk management systems and plans. This first major revision is based on the experience gained since the Agency's PRAC started its operations. Together with GVP module V, EMA is also consulting stakeholders on an amended Risk Management Plan ("RMP") template, to be used by medicine developers. After comments have been received from stakeholders during the public consultation, the Agency will publish the final versions of GVP module V and the RMP template together with an implementation plan. Until then, the current versions of GVP module V and the RMP template remain applicable. ***Comments are due May 31, 2016***.

EMA Consults on Medicines for Autism Spectrum Disorder
On March 4, 2016, EMA released a guideline on the clinical development of medicines for the treatment of Autism Spectrum Disorder for a six-month public consultation. This is the first guidance document issued by the CHMP for developers of medicines targeting autism. The draft guideline provides advice on diagnosis and inclusion criteria for the selection of patients, methods for assessment of the efficacy of medicines, design of clinical trials, and evaluation of clinical safety. ***Comments are due August 31, 2016***.

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Amarin and FDA Agree to Landmark Settlement on Off-Label Promotion

On March 8, 2016, Amarin Pharma, Inc. reached a noteworthy settlement in its lawsuit against the U.S. Food and Drug Administration ("FDA") to protect its First Amendment right to promote the drug Vascepa for nonapproved, off-label uses. *Amarin Pharma, Inc. v. FDA* (S.D.N.Y. No. 15-cv-3588) (Engelmayer, J.). Earlier, Judge Engelmayer had granted a preliminary injunction blocking FDA from pursuing a misbranding suit against Amarin for the company's off-label promotion. This recent settlement now brings the litigation to a close—signaling a potential softening in FDA's stance on off-label promotion and, potentially, a more active role for the courts in determining when off-label promotion is permitted.

Case Background

FDA approved Vascepa (icosapent ethyl) capsules to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. The original approval was based on a single Phase 3 clinical trial of patients with "very high" triglycerides, which was conducted under a Special Protocol Assessment ("SPA") agreement with FDA. An SPA indicates FDA agreement that a study will support the approval of a drug product's application if the study is conducted in accordance with the protocol and achieves the agreed-upon objectives. Subsequently, Amarin designed and entered an SPA with FDA to evaluate the effect of Vascepa on triglyceride levels among statin-treated patients with "persistently high" triglycerides (>200 and <500 mg/dL) in a single Phase 3 clinical investigation. Amarin also agreed to conduct a cardiovascular outcomes trial on these patients.

Amarin submitted a supplemental application in February 2013, requesting FDA approval for use of Vascepa in patients with persistently high triglycerides. The application detailed the data from the studies conducted pursuant to the SPA, which met the primary endpoint, a significant secondary endpoint, and the obligations associated with the cardiovascular outcomes study. Often, SPA compliance leads to approval. Not here, however. Instead, FDA seemed to have second thoughts about the underlying science. Specifically, FDA did not feel the data sufficiently supported the drug's use in patients with persistently high triglycerides and rescinded the SPA, an extremely rare occurrence. In a Complete Response Letter, the agency stated that it needed additional data before it could approve the second use. It also warned Amarin that any effort to promote Vascepa for the unapproved use could constitute misbranding under the Food, Drug and Cosmetic Act.

Ten days after receiving the letter, Amarin sued FDA. The company claimed that the First Amendment protected its right to tell doctors and other health care professionals about the data suggesting that Vascepa could be used to treat persistently high triglycerides. According to Amarin's complaint, FDA's threat of a misbranding prosecution for the truthful, non-misleading promotion of an off-label use had an impermissible chilling effect on the company's constitutionally protected speech. Amarin sought a preliminary injunction barring FDA from pursuing such a claim.

The August 7, 2015 Ruling

In granting Amarin's motion for a preliminary injunction, Judge Engelmayer relied heavily on the U.S. Court of Appeals for the Second Circuit's ruling in *United States v. Caronia*. The *Caronia* court held that the First Amendment prohibited the government from criminally prosecuting an individual for the truthful, non-misleading promotion of a drug for off-label uses. In Amarin's case, the government essentially sought to limit *Caronia* to its particular facts and procedural posture, focusing on improper instructions and other statements made to the jury there. But Judge Engelmayer read *Caronia* more broadly to disallow any and all misbranding prosecutions for truthful, non-misleading off-label promotion, because, in the Second Circuit's view, the government lacked sufficient justification to prohibit such speech.

Judge Engelmayer then held that certain communications proposed by Amarin were indeed truthful and non-misleading. For certain other communications, Judge Engelmayer provided revisions that would make the statements truthful and non-misleading. But, he emphasized that his rulings were based only on the information before him: "A statement that is fair and balanced today may become incomplete or otherwise misleading in the future as new studies are done and new data is acquired."

Because Judge Engelmayer's ruling was only a decision on a motion for a preliminary injunction, it did not provide any final relief. In addition, FDA was free to appeal to the Second Circuit. Shortly after the ruling was issued, however, Amarin and FDA announced that they were discussing a potential settlement.

In the settlement, the government "agree[d] to be bound by the Court's conclusion that Amarin may engage in truthful and non-misleading speech promoting the off-label use of Vascepa … and, under *Caronia*, such speech may not form the basis of a prosecution for misbranding." In addition, the government agreed that Amarin's proposed statements, as modified by the court's August 2015 ruling, were "truthful and non-misleading" and establish a new procedure through which Amarin can seek preapproval from FDA of off-label promotional communications.

For a full discussion on the settlement, please see our recent Jones Day *Alert*. For information related to what this means for industry, please see our Jones Day *Industry Insight*.

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FDA to Conduct Two Studies on DTC Drug Advertising

In early March 2016, FDA published a notice soliciting comments on a planned FDA study titled "Animation in Direct-to-Consumer Advertising." As detailed in the notice, FDA plans to investigate the impact of animation in direct-to-consumer ("DTC") prescription drug advertising on "consumer comprehension, processing, and perception of risk and benefit information." DTC advertising is advertising provided by drug companies aimed at a general audience, as opposed to health care professionals. Specifically, FDA will study the role played by (i) the type of animation used (e.g., live-action human sufferer, rotoscoped human sufferer, or non-human animation) and (ii) an ad's focus on the sufferer, the disease, or the benefit through non-human personification animation.

One week later, FDA published a notice soliciting comments on another planned FDA study titled "Superimposed Text in Direct-to-Consumer Advertising." For this study, FDA plans to investigate the impact of (i) text size, (ii) device type (television or tablet), and (iii) text–background contrast on individuals' perception of the superimposed information's importance, recall of information, and attitudes toward the promoted drug. FDA hopes its research will expand on previous advertising research that may not be applicable to drug promotion, modern video advertising techniques and devices, and the older adult population (which uses the greatest proportion of prescription drugs).

FDA's studies come amid ongoing scrutiny of DTC advertising for prescription drugs and recent cases challenging the traditional bounds of pharmaceutical marketing activities. As we previously highlighted, the American Medical Association adopted a policy in late 2015 calling for a ban on DTC advertising of prescription drugs and medical devices. This was followed in February 2016 with Rep. Rosa DeLauro (D-CT) introducing the Responsibility in Drug Advertising Act of 2016, which would prohibit DTC advertising for three years following a drug's approval and authorize the Secretary to waive or extend the three-year moratorium for public health-related reasons. Most recently, Sen. Al Franken (D-MN) introduced the Protecting Americans from Drug Marketing Act, which would prohibit tax deductions for DTC advertising expenditures. Not surprisingly, industry responses have pointed to the First Amendment, which was recently cited with success in the cases *Amarin Pharma, Inc. v. FDA* (Amarin obtained preliminary injunction and eventually settled with FDA; *see* previous discussion here, here, and here) and *Pacira Pharmaceuticals, Inc. v. FDA* (Pacira and FDA settled; *see* company statement and FDA rescission letter).

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Although the majority of therapeutic biological products have been licensed under the PHSA, some protein products historically have been approved under the FDCA. Under the Biologic Price Competition and Innovation Act (the "Act"), biologic marketing applications must be submitted under § 351 of the PHSA, and existing approvals under the FDCA must be transitioned to licenses under the PHSA. According to the draft guidance, FDA intends to interpret the "deemed to be a license" provision to mean that, on March 23, 2020, applications for biologics under § 505 of the FDCA "will no longer exist" as new drug applications ("NDAs") or abbreviated new drug applications ("ANDAs") and will be replaced by either approved biologic license applications ("BLAs") or abbreviated biologic license applications ("aBLAs").

Notably, the draft guidance outlines how FDA intends to handle unexpired periods of exclusivity (e.g., five-year exclusivity, three-year exclusivity, or pediatric exclusivity) granted to products under the FDCA on or before March 23, 2020. In such a situation, FDA's draft guidance asserts the exclusivity provided under the FDCA would cease to have any effect, and moreover, any patents listed in the Orange Book would no longer be relevant for purposes of determining the timing of approval of a 505(b)(2) application or ANDA. Because orphan drug exclusivity can be granted and prevents drug approval under both the FDCA and the PHSA, unexpired periods of exclusivity would continue with the transitioned products.

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